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EXAMINER

KARPINSKI, LUKE E

ART UNIT

PAPER NUMBER

1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,392	Applicant(s) WANNOWIUS ET AL.	
	Examiner LUKE E. KARPINSKI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10, 15-16, and 21-24 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Claims 1-16 and 21-24 are pending and under consideration in this action.

Claims 17-20 have been canceled by Applicant.

Claims 1 and 11-14 appear to have allowable subject matter.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 recites “peroxide at a pH value of > 6,5, to”, it appears that the comma between 6 and 5 is a typographical error and should have been a decimal point. Appropriate correction is required.

Claim 16 is objected to because of the following informalities: Claim 16 recites “for parental or topical”. It appears that parental is a typographical error and should be parenteral.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-10 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-10 are rejected under 35 USC 112, second paragraph, which paragraph? Same for all below for utilization of the term derivatives. It is unclear what is meant by derivative and the term is not defined in either the claims or the specification.

Claims 4-6, 9, and 22 are rejected under 35 USC 112, second paragraph, for the chemical formulas $\text{O}=\text{ClOOH}$ and $\text{O}=\text{ClOO}^-$. It is unclear what chemical structures are being claimed by these formulas,

Claims 4-6, 9-10, and 22 are rejected under 35 USC 112, second paragraph, for utilization of the chemical name peroxochlorous, in combination with the chemical formulas $\text{O}=\text{ClOOH}$ and $\text{O}=\text{ClOO}^-$. Peroxo implies that said structure has 4 oxygen atoms and the chemical formulas given only have 3. It is unclear what compounds applicant is claiming. For the purposes of a compact prosecution the examiner will search the chemical formulas.

Claim 23 is rejected under 35 USC 112, second paragraph, for claiming an anion. The reasoning for the rejection is that claim 23 is dependant on claim 22, which recites only anions and one cannot have an anion of an anion. Therefore it is not understood what exactly applicant is claiming. Claim 24 is rejected for being dependant upon an indefinite claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2, 3, 7, 8, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by US Patent Publication No. 2003/0133878 to Hinze.

Hinze discloses aqueous solutions of reactive chlorine compounds (paragraphs [0008] to [0010]) as claimed in claim 2.

Hinze further discloses a dichloric acid (paragraphs [0008] to [0010]) as claimed in claims 3 and 7, salts of said dichloric acids (paragraph [0008]) as claimed in claim 8, a pharmaceutical preparation comprising an aqueous solution according to claim 2 (abstract and paragraphs [0008]-[0010]) as claimed in claim 15.

Claims 2, 3, 7, 8, and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by International publication No. WO03/050044 to Hinze.

Hinze discloses aqueous solutions of reactive chlorine compounds (abstract and page 6, lines 5-25) as claimed in claim 2.

Hinze further discloses a dichloric acid (page 6, lines 5-25) as claimed in claims 3 and 7, salts of said dichloric acids (page 4, line 17 to page 5, line 5) as claimed in claim 8, a pharmaceutical preparation comprising an aqueous solution according to claim 2 (abstract and page 6, lines 5-25) as claimed in claim 15.

Claims 2, 4, 9, 15 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by US Patent No. 5,695,752 to Rosen et al.

Rosen et al. disclose aqueous solutions of reactive chlorine compounds (chlorate, which has the formula ClO_3^-), (abstract) as claimed in claim 2, 4, and 9. Claim

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9 is rejected based on the structure of claim 4 not the term peroxochlorous acid. Rosen et al. further disclose said formulations as injectable pharmaceuticals (abstract) as claimed in claims 15 and 16.

Claims 2-7, 9, 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Davidson et al., "An investigation of Photochemically Induced Reactions in a Chlorine-Ozone System at 10.5 and 0.0 degrees".

Davidson et al. disclose aqueous solutions comprising reactive chlorine compounds (introduction) as claimed in claim 2, anions of $\text{H}_2\text{Cl}_2\text{O}_6$ (introduction, first paragraph) as claimed in claims 3, 7, 21, and 23, aqueous solutions comprising $\text{O}=\text{ClOO}^-$ (introduction, first and last paragraph) as claimed in claims 4 and 9, and aqueous solutions comprising both $\text{H}_2\text{Cl}_2\text{O}_6$ and $\text{O}=\text{ClOO}^-$ (introduction) as claimed in claims 8. Regarding the structures of claim 21, an anion of the formula $\text{H}_2\text{Cl}_2\text{O}_6$, would inherently have at least one of the structures given in instant claim 21, as can be seen in the STIC search results answer 17 of 28, which is the Davidson et al. reference, when structure III was searched. Such a solution would also inherently also comprise of structures II which is simply a resonance structure of structure III.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2003/0133878 to Hinze.

Applicant Claims

Applicant claims chlorine compounds and aqueous solutions thereof comprising dichloric acids of the formula $\text{H}_2\text{Cl}_2\text{O}_6$, and four specific chemical structures for the anions of said dichloric acids. Applicant also claims salts, anions, and derivatives of these compounds.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hinze teaches the chemical formula $\text{Cl}_2\text{O}_6^{2-}$ (paragraph [0010]) as pertaining to claim 21, and salts of said compounds in claim 21 (paragraph [0008]-[0010]) as pertaining to claims 23 and 24.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Hinze does not teach specific structures of chlorine compounds as claimed in claim 21. However, Hinze does teach the chemical formula $\text{Cl}_2\text{O}_6^{2-}$, as well as, salt of this formula.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding claim 21, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Hinze with chlorine compounds having the structural formulas found in instant claim 21 in order to produce the invention of instant claim 21.

One of ordinary skill in the art would have been motivated to do this because Hinze teaches the chemical formula of said claimed compounds and there are a limited number of structural compounds which can be produced having such a chemical formula. Further, by not claiming any specific structural formula, Hinze envisions all of the possible structural formulas that said chemical formulas may produce. Therefore it would have been obvious to utilize the any structural formula, which also meets the limitations of the chemical formula $\text{Cl}_2\text{O}_6^{2-}$, in the formulations of Hinze in order to provide said formulation with a radical anion species having a designated redox potential.

Regarding claims 23 and 24, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Hinze with salts of chlorine compounds having the structural formulas found in instant claim 21 in order to produce the invention of instant claims 23 and 24.

One of ordinary skill in the art would have been motivated to do this because Hinze teaches salts of the chemical formula of said claimed compounds, including potassium salts, which read on alkaline metal salts. Therefore it would have been obvious to utilize salts of chlorine compounds in the formulations of Hinze in order to provide said formulation with a radical anion species having a designated redox potential.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

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one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over International publication No. WO03/050044 to Hinze.

Applicant Claims

Applicant claims chlorine compounds and aqueous solutions thereof comprising dichloric acids of the formula $\text{H}_2\text{Cl}_2\text{O}_6$, and four specific chemical structures for the anions of said dichloric acids. Applicant also claims salts, anions, and derivatives of these compounds.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hinze teaches the chemical formula $\text{Cl}_2\text{O}_6^{2-}$ (page 6, lines 5-25) as pertaining to claim 21, and alkali salts of said compounds in claim 21 (page 4, lines 17 to page 5, line 5) as pertaining to claims 23 and 24.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Hinze does not teach specific structures of chlorine compounds as claimed in claim 21. However, Hinze does teach the chemical formula $\text{Cl}_2\text{O}_6^{2-}$, as well as, salt of this formula.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Regarding claim 21, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Hinze with chlorine compounds having the structural formulas found in instant claim 21 in order to produce the invention of instant claim 21.

One of ordinary skill in the art would have been motivated to do this because Hinze teaches the chemical formula of said claimed compounds and there are a limited number of structural compounds which can be produced having such a chemical formula. Further, by not claiming any specific structural formula, Hinze envisions all of the possible structural formulas that said chemical formulas may produce. Therefore it would have been obvious to utilize the any structural formula, which also meets the limitations of the chemical formula $\text{Cl}_2\text{O}_6^{2-}$, in the formulations of Hinze in order to provide said formulation with a radical anion species having a designated redox potential.

Regarding claims 23 and 24, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Hinze with salts of chlorine compounds having the structural formulas found in instant claim 21 in order to produce the invention of instant claims 23 and 24.

One of ordinary skill in the art would have been motivated to do this because Hinze teaches salts of the chemical formula of said claimed compounds, including

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alkaline metal salts. Therefore it would have been obvious to utilize salts of chlorine compounds in the formulations of Hinze in order to provide said formulation with a radical anion species having a designated redox potential.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,695,752 to Rosen et al.

Applicant Claims

Applicant also claims salts of the chlorine compounds of claim 9 and a specific concentration for said aqueous compositions.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Rosen et al. teach aqueous pharmaceutical chlorate solutions for injection (abstract).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Rosen et al. do not teach salts of said chlorates or concentrations of said chlorates. However, Rosen et al. do teach that said formulations are aqueous and that they are for injection into a mammal.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Regarding claim 10, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Rosen et al. with salts of chlorates in order to produce the invention of instant claim 21.

One of ordinary skill in the art would have been motivated to do this because Rosen et al. teach aqueous formulations and it is well known in the art that salts of compounds are easier to work with than free bases. Therefore it would have been obvious to utilize a salt of said chlorate in the formulations of Rosen. Further, aqueous solutions contain cations, as well as, anions and metals are common cation impurities in aqueous solutions, therefore a metallic salt would necessarily be present in the formulations of Rosen et al.

Regarding claim 22, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the formulations of Rosen et al. with a concentration of 0.01M in order to produce the invention of instant claim 22.

One of ordinary skill in the art would have been motivated to do this because Rosen et al. teach that said formulations are injected and one of ordinary skill in the art, being a physician, would know the proper range of concentrations at which such a

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formulation could be safely injected into a patient, which would include 0.01M.

Therefore it would have been obvious to formulate a solution having 0.01M chlorine concentration in the formulations of Rosen et al., in order to provide a formulation safe for injection into a patient..

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson et al., "An investigation of Photochemically Induced Reactions in a Chlorine-Ozone System at 10.5 and 0.0 degrees". The rejection is over the author and not the title of the article. Correct this, all occurrences.

Applicant Claims

Applicant claims chlorine compounds and aqueous solutions thereof comprising dichloric acids of the formula $\text{H}_2\text{Cl}_2\text{O}_6$, or compounds having the formula $\text{O}=\text{ClOO}^-$, said chlorine compounds having a concentration of at least 0.01M.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The disclosure of Davidson et al. is delineated above. In particular Davidson et al. teach anions of $\text{H}_2\text{Cl}_2\text{O}_6$ (introduction, first paragraph), aqueous solutions comprising $\text{O}=\text{ClOO}^-$ (introduction, first and last paragraph), and aqueous solutions comprising both $\text{H}_2\text{Cl}_2\text{O}_6$ and $\text{O}=\text{ClOO}^-$ (introduction).

***Ascertainment of the Difference between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Davidson et al. do not teach the aqueous solutions of chlorine compounds having a concentration of at least 0.01M.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Regarding claim 22, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the chlorine solutions of Davidson et al. with at least a 0.01M concentration in order to produce the invention of instant claim 22.

One of ordinary skill in the art would have been motivated to do this because it is a common practice in the field of chemistry to make solutions of different concentrations and one of ordinary skill would have readily known how to make a wide variety of different concentrations of such chlorine solutions, as well as, the fact that one would be motivated to do so in order to increase or decrease the oxygenating power of said solution. Therefore it would have been obvious to utilize a concentration of at least

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0.01M chlorine solution with the solutions of Davidson et al. in order to impart the oxygenating effect that said chlorines solutions have at said concentration.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter.

With respect to claims 1 and 11-14, the prior art fails to teach or explicitly disclose either singly or in combination a method for the preparation of aqueous solutions of reactive chlorine compounds comprising the steps recited in instant claims 1 and 11-14.

Conclusion

Claims 1 and 16 are objected to.

Claims 2-6, 7-10, 15-16, and 21-24 are rejected.

Claims 17-20 have been canceled by applicant.

Claims 1, and 11-14 appear to contain allowable subject matter

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Thursday 9-4 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616